

## **REMARKS/ARGUMENTS**

### **Restriction Requirement**

In response to the lack of unity rejection raised by the Examiner, claims 1, 5 to 6, and 8 to 26 relating to non-elected inventions are now indicated as withdrawn.

In the Office Action, the Examiner has designated claim 3 (drawn to isolated vectors comprising the polynucleotide of claim 2) as withdrawn from consideration for being drawn to a non-elected invention. However, in the restriction requirement of June 12, 2008 and in applicants' response, the elected invention of Group II (claims 2-5, 7, 27, and 28) was defined as encompassing isolated polynucleotide encoding the polypeptide of claim 1, as well as vectors, host cells and methods requiring the same. Accordingly, accordingly applicants believe claim 3 is properly considered in the present application. Clarification is respectfully requested.

### **Objections to the Specification**

The Examiner objects to the specification (p. 24, line 15, p. 24, line 28, and p. 41, line 28) for including "an embedded hyperlink and/or other form of browser-executable code". The specification has been amended to remove the browser-executable code from page 24, line 15 and page 41, line 28. However, page 24, line 28, simply recites "www.ncbi.nlm.nih.gov/BLAST/", which is not executable. MPEP 608.01 does not prohibit a world wide web address in a patent application unless it is executable. Therefore, the objection to this phrase is improper and the phrase has not been amended.

### **Objections to the claims**

The Examiner objects to claims 27 and 28 for containing grammatical errors. Claim 27 has been amended to remove the phrase objected to in the Office Action. Claim 28 has been amended, as suggested by the Examiner. Withdrawal of the rejections in view of theses amendments is respectfully requested.

### **Rejections under 35 U.S.C. § 101**

Claims 4, 5, and 7 stand rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. According to the Examiner, claims 4, 5, and 7 read on product of

nature, namely cells found in intact mammals, including humans that received the vector, and polynucleotides found in nature. The Examiner suggests defining the host cells as “purified” or “isolated” so as to distinguish from products found in nature.

To expedite prosecution, applicants have amended claims 3 and 4 in accordance with the Examiner’s suggestion. Withdrawal of the rejection in view of the amendments is respectfully requested.

**Rejections under 35 U.S.C. § 112, First Paragraph**

**Written Description:**

Claims 2, 4, 5, 7, 27, and 28 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. To expedite prosecution, claim 2 has been amended to be directed to “a polynucleotide comprising the nucleotide sequence of SEQ ID NO:1.” Further, the polynucleotide of claims 27 and 28 have been amended in the same way. Applicants, however, specifically reserve the right to pursue the original claims in one or more subsequent applications. In view of the amendments and remarks, withdrawal of the rejection is respectfully requested.

**Enablement:**

Claims 27 and 28 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. According to the Examiner, the guidance and examples in the specification are insufficient to support the claimed “treatment and prevention of pancreatic cancer”, more particularly the induction of an anti-tumor immune response through the administration of a polypeptide or polynucleotide as claimed. Essentially, the Examiner challenges the correlation between the disclosed *in vitro* results and the proposed *in vivo* strategy, asserting that “[o]ne of skill in the art could not reasonably extrapolate from the results of the administration of siRNA *in vitro* to cell lines to the pharmaceutical properties of a C1958V1 polynucleotide *in vivo*.” It is well established that *in vitro* results can be used to establish therapeutic efficacy when the results are reasonably correlated with efficacy. Nonetheless, to expedite prosecution, claim 27 has been amended to reference to treatment of disease and refer simply to “a composition comprising the polynucleotide of claim 2”.

Withdrawal of the outstanding rejection in view of the above amendments is respectfully requested.

**Rejections under 35 U.S.C. § 102**

Claims 2 and 7 stand rejected under 35 U.S.C. § 102(a) as being anticipated by the following prior art disclosures.

GenBank Accession No. BQ671560, publicly available on July 15, 2002

GenBank Accession No. BQ672221, publicly available on July 15, 2002

GenBank Accession No. BI914593, publicly available on October 16, 2001

According to the Examiner, the polynucleotides of GenBank Accession No. BQ671560 and BQ672221 each encode a polypeptide that is 100% identical to Applicants' SEQ ID NO: 2. Further, the Examiner states that the polynucleotide of GenBank Accession No. BI914593 encodes a polypeptide that is 88.6% identical to Applicants' SEQ ID NO: 2.

Claim 2 has been amended to recite "a polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1." Claim 7 has been deleted. As demonstrated in the attached Appendix A, the nucleotide sequence of SEQ ID NO: 1 differs from those described in the cited prior art. Accordingly, withdrawal of the rejection in view of the amendments is respectfully requested.

**REJECTIONS UNDER 35 U.S.C. § 103**

Claims 2, 4, 5, 27 and 28 stand rejected under 35 U.S.C. § 103(a) as being obvious over GenBank Accession No. BQ671560 in view of Ausubel *et al.* (Curr. Prot. In Mol. Biol., 1995). According to the Examiner, it would have been obvious for one of ordinary skill in the art to manipulate the BQ671560 sequence to provide a vector, host cell or pharmaceutical composition comprising the BQ671560 polynucleotide sequence or a polypeptide encoded thereby.

As noted above, claims 2 and 27 have been amended to be directed to a polynucleotide comprising the nucleotide sequence of SEQ ID NO:1. As indicated in Appendix A, the nucleotide sequence of SEQ ID NO:1 differs from that disclosed in BQ671560. Ausubel *et al.* fails to cure the deficiencies of the BQ671560 sequence. Accordingly, for the reasons

stated above, the invention of the pending claims is not rendered obvious by the disclosure of GenBank Accession No. BQ71560, alone or in combination with Ausubel. Withdrawal of the rejection is respectfully requested.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,

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